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Mi Kyong Shin

PATENT

Attorney Docket No. 12636.219

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)	<u>PATENT APPLICATION</u>
)	
Inventor(s): Jorge DIMARTINO et al.)	
)	Art Unit: 1623
Application No.: 09/976,468)	
)	Examiner: Patrick T. Lewis
Filed: October 12, 2001)	
)	Confirmation No.: 9964
Title: Composition and method for treating)	
graft-versus-host disease)	
)	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

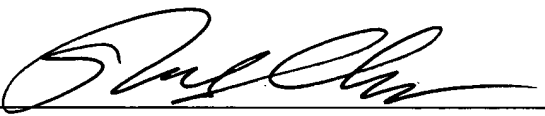
- ☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
 - ☐ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☒ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; or
 - ☒ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
 - B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.
 - ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
 - ☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed.)

- ☐ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636.219).

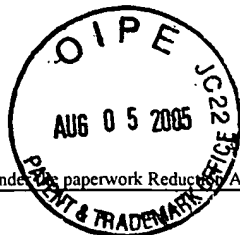
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: Aug. 2. 2005

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PTO/SB/08A (08-03)

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/976,468
				Filing Date	10/12/2001
				First Named Inventor	DiMartino et al.
				Art Unit	1623
				Examiner Name	Lewis
Sheet	1	of	4	Attorney Docket Number	12636.219

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ABE, Y. et al., "Eradication of virus-infected T-cells in a case of adult T-cell leukemia/lymphoma by nonmyeloblastic peripheral blood stem cell transplantation with conditioning consisting of low-dose total body irradiation and pentostatin", Case Report, <i>International Journal of Hematology</i> , (July 2002), 76(1):91-93	
		ALCINDOR, T. et al., "Engraftment and immunologic effects a novel less myeloablative allogeneic transplant conditioning regimen of continuous infusion pentostatin, photopheresis, and low dose TBI", <i>PROC. Blood</i> , (2000), 96(11):327a, abst 5160.	
		BAYER, R. et al., "Pentostatin based non-myeloablative conditioning regimen in patients with high-risk hematologic malignancy", <i>Proc of ASH</i> , (2000), 96(11):327, abst 5163.	
		BOCIEK, G.R. et al., "Nonmyeloablative allogeneic stem cell transplantation (NST) for lymphoid malignancies using pentostatin/low-dose total body irradiation, <i>BB&MT</i> , (February 2004), 10(2), Supplement 1, page 27.	
		CHAN, G. et al., "Decreased acute and chronic graft versus host disease with early full donor engraftment following a pentostatin-based preparative regimen for allogeneic bone marrow transplant in high-risk patients", <i>Proc Blood</i> , (2001), 98(11):383a, abst 1612.	
		CHAN, G.W. et al., "Age is not associated with adverse outcomes following pentostatin-based preparative regimen for allogeneic bone marrow transplant", <i>Proc Blood</i> , (2001), 98(11):313b, abst 5011.	
		CHAN, G.W. et al., "Even coagulase negative staphylococcus infections following reduced intensity transplantation are associated with increased transplant complications and poorer overall survival", <i>BB&MT</i> , (February 2004), 10(2), Supplement 1, page 11.	
		CHAN, G.W. et al., "Extracorporeal photopheresis, pentostatin and total body irradiation reduced intensity transplantation in relapsed or refractory AML patients: evidence for early graft versus tumor effect with less GVHD", <i>Blood</i> , (November 16, 2003), 102(11), abst 3265.	
		CHAN, G.W. et al., "Grade 2-4 acute graft-versus-host disease and extensive chronic graft-versus-host disease are associated with significantly decreased survival following reduced intensity allogeneic stem cell transplantation", <i>Blood</i> , (November 16, 2004), abst 1246.	

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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		CHAN, G.W. et al., "MDS patients undergoing a novel reduced intensity allogeneic bone marrow transplant achieves complete remission with less transplant toxicity and graft versus host disease", <i>Proc. ASH</i> , (2002), abst 2450.	
		CHAN, G.W. et al., "Persistence of host dendritic cells after transplantation is associated with graft-versus-host disease", (2003), 9:170-176.	
		CHAN, G.W. et al., "Reduced-intensity transplantation for patients with myelodysplastic syndrome achieves durable remission with less graft-versus-host disease", <i>Biology of Blood and Marrow Transplantation</i> , (2003), 9:753-759.	
		CHAN, G.W. et al., "Targeting host antigen-presenting cells pre-transplant reduces graft versus host disease", <i>BB&MT</i> , (2002), 8(2).	
		CHIN, K.M. et al., "Favorable outcomes in matched unrelated donor allogeneic stem cell transplantation using a pentostatin/extracorporeal photopheresis based reduced intensity conditioning regimen", <i>Blood</i> , (November 16, 2003), 102(11), abst 1758.	
		EPSTEIN, J. et al., "Prevention of graft-versus-host disease in allogeneic bone marrow transplantation by pretreatment with 2'-deoxycoryformycin", <i>Exp. Hematol.</i> , (1986), 14:845-849.	
		FOSS, F. et al., "Novel pentostatin/extracorporeal photopheresis based allogeneic conditioning regimen for high risk non-Hogkin's lymphoma", <i>Annals of Oncology</i> , Vol. 13, Supp. 2, page 167, Abst 597.	
		FOSS, F. et al., "Novel pentostatin/extracorporeal photopheresis reduced intensity conditioning regimen: results in relapsed/refractory NHL", <i>Proc. ASH</i> , (2002), abst 413.	
		LIU, D. et al., "Graft-versus-lymphoma effect yields high percentage of durable complete remission in high risk patients following mini-transplantation with MAP (mitoxantrone, ARA-C, and pentostatin) regimen", <i>BB&MT</i> , (February 2004), 10(2), Supplement 1, page 35.	
		MILLER, K., "Reduced intensity allogeneic transplants", <i>Cancer Investigation</i> , (November 2002), Vol. 21, Supp. 1, pages 97-99.	

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Sheet	3	of	4	Attorney Docket Number		12636.219

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		MILLER, K.B. et al., "Allotransplants: a novel reduced intensity regimen", <i>Cancer Investigation</i> , (November 2000), Vol. 20, Supp. 1, abst 82.	
		MILLER, K.B. et al., "Reduced intensity conditioning regimens – a novel reduced intensity regimen for allogeneic hematopoietic stem cell transplantation associated with a reduced incidence of graft-versus-host disease", <i>Bone Marrow Transplantation</i> , (2004), 33:881-889.	
		PAVLETIC, S.Z. et al., "Immunological effects of pentostatin in a minimally myelosuppressive regimen for allogeneic stem cell transplantation", <i>Proc. ASH</i> , (2002), abst 2446.	
		PAVLETIC, S.Z. et al., "Immunomodulatory effects of pentostatin in a regimen for non-myeloablative stem cell transplantation", 3 rd International Workshop on iwNST held on January 18-21, 2002 in Captiva Island, FL, 1 page.	
		PAVLETIC, S.Z. et al., "Lymphodepleting effects and safety of pentostatin for nonmyeloablative allogeneic stem-cell transplantation", <i>Brief Communications, Transplantation</i> , (September 15, 2003), 76(5):877-881.	
		"Pentostatin effective as preparative regimen for kidney transplant", <i>Expert Review of Anticancer Therapy</i> , (2001), 1(4):508.	
		RAO, R. et al., "Cytomegalovirus reactivation and relapse following allogeneic stem cell transplantation using a reduced intensity conditioning regimen", <i>Blood</i> , (November 16, 2004), 104(11), abst 5104.	
		ROBERTS, T.F. et al., "A novel preparative regimen associated with reduced morbidity and mortality following allogeneic bone marrow transplant", <i>PROC. Blood</i> , (2000), 96(11):781a, abst 3378.	
		ROBERTS, T.F. et al., "Outcome of 48 patients undergoing allogeneic bone marrow transplant with a reduced intensity preparative regimen of photopheresis, continuous infusion pentostatin and reduced dose TBI", <i>Journal of the American Society for Blood and Marrow Transplantation</i> , (2002), 8(2).	
		RUERS, T.J. et al., "Complete suppression of skin allograft rejection in rats treated with continuous infusion of 2'-deoxycoformycin", <i>Transplantation</i> , (1985), 40(2):137-142.	

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		SANDMAIER, B.M. et al., "Conversion of low donor chimerism following nonmyeloablative conditioning for hematopoietic cell transplantation (HCT) using pentostatin and donor lymphocyte infusion (DLI)", <i>Blood</i> , (November 16, 2004), 104(11), abst 186.	
		SCHILLER, G.J. et al., "Letter to the editor re allogeneic transplantation after nonmyelosuppressive conditioning—the effect of single-agent pentostatin", <i>BB&MT</i> , 10:576-577.	
		SCHILLER, G.J. et al., "Transplantation of allogeneic peripheral blood progenitor cells after non-myelosuppressive preparative conditioning-A phase I/II trial of single-agent pentostatin as an innovative preparative regimen for allogeneic transplantation for kidney cancer", <i>Proc of ASH</i> , (2001), 98(11):184a, abst 773.	
		SCHWARTZ, J.E. et al., "Pentostatin and cyclosporine, a new regimen for the prevention of acute graft-versus-host disease after allogeneic peripheral blood progenitor cell transplantation", <i>BB&MT</i> , (February 2004), 10(2), Supplement 1, page 50.	
		SCHWARTZ, J.E. et al., "Pentostatin and cyclosporine for prevention of acute graft-versus-host disease after allogeneic peripheral blood progenitor cell transplantation", <i>Blood</i> , (November 16, 2003), 102(11), abst 5524.	

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